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PATENT
ATTORNEY DOCKET NO. 00654759**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re Application of:
Maor, et al.

Serial No.: 09/582,522

Filing Date: April 10, 2000

For: A GEL COMPOSITION FOR
SKIN CARE AND PROTECTION
AND A METHOD OF
PREPARATION THEREOFGroup Art Unit:
1617Examiner:
Yu, DMail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**DECLARATION #3 UNDER 37 C.F.R. § 1.132 OF SHLOMO MAGDASSI**

1, Shlomo Magdassi of 36 Hamered Street, Jerusalem, Israel, an Israeli citizen declare hereinafter in writing as follows:

1. I am Associate Professor at the Hebrew University in Jerusalem.

2. My Curriculum Vitae was previously submitted in connection with the my first

Declaration, filed November 26, 2003.

3. I am one of the inventors of the above captioned Application No. 09/582,522.

4. The present invention relates to a novel gel comprising at least Dead Sea water, a hydrophobic active agent, and a non-ionic solubilizer, wherein the gel is a clear gel.

5. It has been known in the art to provide a composition for the treatment of the skin that incorporates the therapeutic benefits of Dead Sea water and the moisturizing effects of hydrophobic active agents. See, e.g., Kyotaro, JP Abstract 08113530, which discloses a bath comprising Dead Sea water and hydrophobic active agents. Kyotaro does not discuss a gel composition, nor does it discuss how one would make a transparent gel composition.

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6. It should be noted that while Kyotaro et al., discloses bath salts which are solid compositions in the forms of coarse powders or slurries, the present invention concerns liquid, gel, compositions which are *a priori* transparent, without need for dilution in water.

7. The Kyotaro et al publication is intended for a totally different purpose than the gel of the present invention. While Kyotaro et al is intended to be dissolved as bath salts in bath water, at very low concentrations (30 g for 200 liters of water) the composition of the present invention is intended for direct application to the skin. As indicated for example on page 9 of the present application which reads: *"The present composition offers the added benefit of being able to 'wear' the composition on the skin for many hours, thus being exposed to the benefits of the dead sea minerals for a longer time, enhancing their action towards skin care and protection"*.

8. In order to emphasize the differences between the present invention and the bath salts of Kyotaro, the compositions appearing in Tables 1, 2 and 3 of Kyotaro et al, publication were prepared in my lab under my supervision. As the Kyotaro et al compositions do not contain a hydrophobic agent (beyond fragrance) we added to each of the Kyotaro formulations 0.6 wt vitamin E acetate (after diluting 30g in 200 liter water), which is the hydrophobic composition used in the present applications.

The following are the results:

Composition 1 (according to table 1 and 2 of Kyotaro et al, comparative case 1)

KCl 5
NaCl 5
(Na) methasilicate 2
glycerine 1
fragrance 0.9
Dead Sea water 20
Na₂SO₄ 66.1

Result : solid, coarse and inhomogeneous powder.

After adding to water (30g in 200 liter water), a very dilute solution is obtained. After adding 0.6% Vitamin E acetate- phase separation occurs, and droplets of the vitamin are observed (no transparency, and no gel). Obviously, this is different from our compositions as this composition is neither gel nor in a clear form.

Composition 3 (according to table 3 Of Kyotaro et al, implement case 7)

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2

KCl 8
NaCl 5
CMC 0.1
glycerine 1
fragrance 0.9
Dead Sea water 60
Na₂SO₄ 25

Result : White, non transparent slurry.

After adding to water (30g in 200 liter water), a very dilute and clear solution is obtained. However, after adding 0.6% Vitamin E acetate- phase separation occurs, and droplets of the vitamin are immediately observed (no transparency during shaking, and no gel). Obviously, this is different from our compositions.

9. As can be seen the compositions of Koyotaro et al are different from those of the present invention in the following:

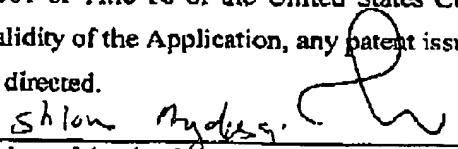
- a. The Koyotaro et al compositions are intended to be used as bath salts (dilution in water and soaking for short time periods), while the composition of the present invention are intended for "leave-on" applications on the skin for prolonged periods of time.
- b. The Koyotaro et al compositions are initially in solid form (coarse powder) or coarse slurries while those of the present invention are liquid, clear gel.
- c. Even after dilution in water the, Koyotaro et al compositions are not in a gel form.
- d. The compositions of Koyotaro et al do not contain significant amount of hydrophobic material (beyond minute amounts of fragrance), while the compositions of the present invention contain hydrophobic materials as part of their cosmetic properties).
- e. The comparative experiments shown above in paragraph 8, demonstrate that even if hydrophobic agents are added to Koyotaro et al (and these agents are not mentioned in the publications) the results is not a gel and in present of the hydrophobic vitamin homogenous clear gel.

10. In the Advisory action mailed July 28,2004 the examiner indicated that in my previous declaration, only two non-ionic surfactants were mentioned . As described in the first declaration, the MSc thesis of one of my students Mr. Yehuda Shaul, is directed to the finding that addition of ionic surfactants to dead sea water causes precipitation so that the resulting composition is opaque.

11. We found that addition of nonionic surfactants such as ethoxylated sorbitan esters (such as Tween 20, Tween 80) and PEG - hydrogenated castor oil (such as Arlatone 650, Arlatone 975) allows obtaining transparent systems, in which the hydrophobic component, such as vitamin E acetate is solubilized.

12. In general, we found that it is possible to solubilize vitamin E acetate in Dead sea salt solution, while using the nonionic surfactants, and the transparency depends on the salt, vitamin and thickening agent concentrations. . In general, the transparency is caused by a change of the cloud point of the system. Thus the property of maintaining the transparency is not unique to TWEEN20 and TWEEN80 mentioned in my previous declaration, and our lab results show that many additional non-ionic surfactant are suitable.

13. I hereby declare that all statements made herein of my own knowledge and are based on the Master's thesis of Y. Shaul, are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that willful false statements may jeopardize the validity of the Application, any patent issuing thereof, or any patent to which this verified statement is directed.


Shlomo Magdassi

Executed this 28 day of September, 2004.